AUG - 8 2007

510(k) Summary for
N Latex RF Kit

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K071247

1. Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation:

Manufacturer:
Dade Behring Marburg GmbH
Emil-von-Behring Str. 76
35041 Marburg, Germany

Contact Information:
Dade Behring Inc.
P.O. Box 6101
Newark, Delaware 19714-6101
Attn: Helen Lee
Tel: 302-631-8706
Fax: 302-631-6299

Preparation date: July 3, 2007

2.

Device Name: N Latex RF Kit
Common Name: RF reagent
Classification: Class II
Product Code: DHR
Panel: Immunology (82)

3. Identification of the Legally Marketed Device:

N Latex RF – K942328

4. Device Descriptions:

N Latex RF Kit

Polystyrene particles coated with an immunocomplex consisting of human immunoglobulin and antihuman IgG from sheep are aggregated when mixed with samples containing RF. These aggregates scatter a beam of light passed through the sample. The intensity of the scattered light is proportional to the concentration of the respective protein in the sample. The result is evaluated by comparison with a standard of known concentration.

5. Device Intended Uses:

N Latex RF Kit

Quantitative determination of rheumatoid factors (RF) in human serum, lithium heparin and EDTA plasma on the BN™ II and BN ProSpec® Systems as an aid in the diagnosis of rheumatoid arthritis.

6. Medical device to which equivalence is claimed and comparison information:

The N Latex RF Kit is substantially equivalent to the currently marketed N Latex RF device (K942328). The N Latex RF Kit, like the currently marketed N Latex RF assay, is an *in vitro* diagnostic test for the quantitative determination of rheumatoid factors (RF) in human serum by means of particle-enhanced immunonephelometry using the BN™ Systems as an aid in the diagnosis of Rheumatoid Arthritis.

7. Device Performance Characteristics:

The N Latex RF Kit was compared to the current N Latex RF assay on the BN™ II System by evaluating serum samples with concentrations ranging from 15.8 to 589.8 IU/mL. Additionally, 43 of these same serum samples, with results ranging from 15.8 to 98.4 IU/mL, were evaluated by Passing-Bablok regression to demonstrate correlation at levels closer to the clinical cutoff. Regression analysis of these results yielded the following results:

	n	Slope	Intercept	Correlation Coefficient
N Latex RF Kit	90	1.098	-12.94	0.98
Results ≤100 IU/mL	43	0.992	-6.81	0.87

8. Conclusion:

Based upon the results of performance studies the N Latex RF Kit is substantially equivalent to the predicate device, N Latex RF.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG - 8 2007

Dade Behring, Inc.
c/o Ms Helen Lee
Manager, Regulatory Affairs and Compliance
Glasgow Site
P.O. Box 6101
Newark, DE 19714-6101

Re: k071247
Trade/Device Name: N Latex RF Kit
Regulation Number: 21 CFR 866.5775
Regulation Name: Rheumatoid factor immunological test system
Regulatory Class: Class II
Product Code: DHR
Dated: July 03, 2007
Received: July 05, 2007

Dear Ms. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The

FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications Statement

K071247

Device Name: **N Latex RF Kit**

Indications for Use:

Quantitative determination of rheumatoid factors (RF) in human serum, heparinized and EDTA plasma on the BN™ II and BN ProSpec® Systems as an aid in the diagnosis of rheumatoid arthritis.

Prescription Use __X__ (Per 21 CFR 801 Subpart D)

Over-The-Counter-Use _____ (21 CFR 801)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

(Optional) K071247